DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 9, 2015

Creche Innovations
c/o Ms. Rebecca K. Pine
Vice President
17745 Metcalf One Penguin Plaza
Stilwell, Kansas 66085

Re: K150484
Trade/Device Name: Penguin In-Line Warmer
Regulation Number: Unclassified, Preamendment
Regulation Name: Thermal Infusion Fluid Warmer
Regulatory Class: Unclassified, Preamendment
Product Code: LGZ
Dated: April 7, 2015
Received: April 10, 2015

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act.
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must
comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150484

Device Name
Penguin In-Line Warmer

Indications for Use *(Describe)*
The Penguin In-Line Warmer is an electrically powered dry warmer which supplies external heat to the plastic tubing of enteral nutrition administration sets.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510K NUMBER:	K150484
APPLICANT:	Creche Innovations
DATE PREPARED:	July 9, 2015
CONTACT PERSON:	Rebecca K Pine 17745 Metcalf One Penguin Plaza Stilwell, KS 66085 Phone: 760.809.5178 Fax: 760.290.3216
TRADE NAME:	Penguin In-Line Warmer
COMMON NAME:	Thermal Infusion Fluid Warmer
CLASSIFICATION NAME:	Unclassified, preamendment
DEVICE CLASSIFICATION:	None
PRODUCT CODE	LGZ
PREDICATE DEVICES:	LiFort LT1 Enteral Nutrition Warmer (K024373) Acacia Enteral Nutrition Warmer (K122449)

Substantially Equivalent To:
The Penguin In-Line Warmer is substantially equivalent in intended use, principal of operation and technological characteristics to the LiFort LT1 Enteral Nutrition Warmer (K024373) and Acacia Enteral Nutrition Warmer (K122449).

Description of the Device Subject to Premarket Notification:

The Penguin In-Line Warmer is an external dry-heat thermal warmer. The Penguin In-Line Warmer warms nutritional feedings for patients being fed via a gastrointestinal tube.

Indication for Use:

The Penguin In-Line Warmer is an electrically powered dry warmer which supplies external heat to the plastic tubing of enteral nutrition administration sets.

Technical Characteristics:

The Penguin In-Line Warmer has similar physical and technical characteristics to the predicate device. The table below illustrates the similarities and differences of the devices.

	Penguin In-Line Warmer	**LiFort LT1 Enteral Nutrition Warmer (K024373)**	**Acacia Enteral Nutrition Warmer (K122449)**
Overall Technological Characteristics	Dry-heat, external thermal warmer.	SAME	SAME
Principle of Operation	The gastrointestinal tubing is fed through the warming channel of the warmer, which warms the nutritional feeding before entering the patient.	SAME	SAME
Power Requirements	240V~, 50/60Hz, 60W/hr 100V~, 50/60Hz, 100W/hr	230V~, 50/60Hz, 60W/hr 115V~, 50/60Hz, 100W/hr	230V~, 50/60Hz, 60W/hr 115V~, 50/60Hz, 100W/hr
Temperature Display	Yes, Celsius and Fahrenheit, LED	No	No
Warming Temperature	36-38C	32-41C	32C-41C
Warming time	2-3 minutes	2-3 minutes	Unknown
Warming patient proximity	At point of care	SAME	SAME
Temperature control	Pre-Set at manufacturer	SAME	SAME
Number of heaters	One	Unknown	One
User controls	ON/OFF button F°/C° button (toggles display)	ON/OFF button	ON/OFF switch
Materials of Construction	Aluminum heating plate	Aluminum heating plate	Heating plate, unknown material(s)
Heating channel	Multi-“S” shaped	“S” shaped	Exaggerated “S” Shape
Tube compatibility	2.0-3.0 dia mm	4.1-5.0 dia mm	2.4mm
Flow rate	0.25-1 ml/min	0-7ml/min	0-7ml/min
Thermal cut-off	Fuse	Fuse	Fuse
Operating Condition	0-40C	0-40C	0-40C
Water resistant case/housing	Yes	Yes	Unknown
Fluid Path Contact	No	SAME	SAME
Direct Patient Contact	No	SAME	SAME
How provided	Non-sterile	SAME	SAME
Reusable	Yes	SAME	SAME

The minor differences in indications for use statements between the Penguin In- line Warmer and that of the predicate devices have no bearing on the safety or effectiveness of the device when used as labeled, as these differences are merely a functional description (such as flow rate and different diameter range of catheters the device can accommodate) and have no effect on the fundamental intended use. All devices share the same intended use, namely, to provide external electrical heat to enteral feeding tubes for the purpose of warming the

nutrition solution.

Performance Data:

All necessary verification and validation testing has been performed for the Penguin In-Line Warmer to assure substantial equivalence to the predicate device. The testing included:

- cleaning/disinfection
- temperature verification
- electrical safety (IEC 60601-1)
- electromagnetic compatibility (IEC 60601-1-2)
- software validation

Basis for Determination of Substantial Equivalence:

Based on the comparable intended use, principle of operation, overall technological characteristics and the performance data provided, the Penguin In-Line Warmer is as safe and effective as the cited predicate devices and is therefore substantially equivalent.